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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/532,873	04/28/2005	Tetsuya Ishii	Q72768	2291
23373 7590 10/09/2007 SUGHRUE MION, PLLC 2100 PENNSYLVANIA AVENUE, N.W. SUITE 800 WASHINGTON, DC 20037			EXAMINER REDDY, KARUNA P	
			ART UNIT 1796	PAPER NUMBER
			MAIL DATE 10/09/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/532,873	Applicant(s) ISHII, TETSUYA	
	Examiner Karuna P. Reddy	Art Unit 1713	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5 and 7-25 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-5 and 7-25 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). _
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>5/7/2007, 8/9/2007</u> . | 6) <input type="checkbox"/> Other: ____ |

INFORMATION DISCLOSURE STATEMENT
U.S. Appln. No.: 10/532,873

Attorney Docket No.: Q72768

The present Information Disclosure Statement is being filed after either a Final Office Action, Notice of Allowance, or an action that otherwise closes prosecution in the application (whichever is earlier), but before payment of the Issue Fee, and therefore Applicant is submitting herewith a check for the fee of \$180.00 under 37 C.F.R. § 1.17(p), and a Statement Under 37 C.F.R. § 1.97(e).

The submission of the listed document is not intended as an admission that any such document constitutes prior art against the claims of the present application. Applicant does not waive any right to take any action that would be appropriate to antedate or otherwise remove any listed document as a competent reference against the claims of the present application.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account. A duplicate copy of this paper is attached.

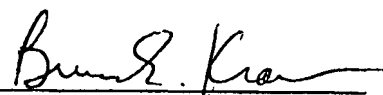
Respectfully submitted,

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WASHINGTON OFFICE

23373

CUSTOMER NUMBER


Bruce E. Kramer
Registration No. 33,725

Date: August 9, 2007

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on September 10, 2007 has been entered.
2. Claims filed on September 10, 2007 are made of record. Claim 6 is cancelled, claim 13 is amended and claims 24-25 are added. Claims 1-5 and 7-25 are currently pending in the application.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
4. Claim 25 is rejected under 35 U.S.C. 102(b) as being anticipated by Ono et al (EP 0 507 160 A1).

Ono et al disclose an adhesive gel base comprising a water-soluble high molecular weight substance and includes polyacrylic acid, a salt of polyacrylic acid. One or more kinds of water-soluble high molecular weight substance are used in the adhesive gel base. Water content is preferably in the range of 10 to 70% (page 3, line 16-27). The water-retaining agent used in the preparation prevents the volatilization of water contained in the adhesive gel base. The water-retaining agent includes, for example, glycols, glycerin and reads on polyhydric alcohol of instant claim (page 3, lines 29-35). See example 1 wherein the adhesive gel comprises sodium polyacrylate, aluminum hydroxide, glycerin and water.

Therefore, Ono et al anticipate the instant invention.

Claim Rejections - 35 USC § 102/103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

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1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. Claims 21-22 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Donati et al (EP 1 046 395 A1).

Donati et al disclose a hydrogel mixture, containing sodium polyacrylate, polyhydrol such as sorbitol, water in the amount of 29.73 wt%, aluminum glycinate (page 4, lines 8-35) and a pharmaceutically acceptable diclofenac salt (page 4, line 1).

The prior art is silent with respect to viscosity of (meth)acrylic acid-base polymer.

However, given that (meth)acrylate acid-base polymer is substantially similar to that of instant invention i.e. sodium polyacrylate meets limitation of the ratio of formula (1) and (2), which is 100/0, and used for similar purposes, one of ordinary skill in the art would have a reasonable basis to believe that the (meth)acrylate acid-base polymer would exhibit similar property. Since PTO cannot conduct experiments, the burden of proof is shifted to the applicants to establish an unobviousness difference. See *In re Fitzgerald*, 619 F.2d 67, 205 USPQ 594 (CCPA 1980).

Even if properties of the (meth)acrylate acid-base polymer of instant claims and prior art examples are not the same, it would still have been obvious to one of ordinary skill in the art to use (meth)acrylate acid-base polymer having the claimed properties because it appears that the references generically embrace the claimed (meth)acrylate acid-base polymer and the person of ordinary skill in the art would have expected all embodiments of the reference to work. Applicants have not demonstrated that the differences, if any, between the claimed (meth)acrylate acid-base polymer and the (meth)acrylate acid-base polymer of prior art give rise to unexpected results.

Claim Rejections - 35 USC § 103

8. Claims 1-5, 7-11, 14, 16, 18 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Donati et al (EP 1 046 395 A1) in view of Ono et al (EP 0 507 160 A1) and Yamazaki et al (JP 08-225443).

Donati et al disclose a hydrogel mixture, containing sodium polyacrylate, polyhydrol such as sorbitol in the range of 40 wt% and water in the amount of 29.73 wt% (page 4, lines 8-35). The cross-linking agent preferably an aluminum compound is in a concentration of 0.01 to 3.0 wt% (page 3, lines 28-29). The composition further contains a pharmaceutically acceptable diclofenac salt (page 4, line 1). The hydrogel mixture preferably comprises a wetting agent chosen from polyhydric alcohols such as glycerol, propylene glycol, sorbitol etc (page 3,

paragraph 0018) in a concentration of 5 to 70 wt% (page 3, paragraph 0019).

The thickening agent includes polyacrylic acid, sodium polyacrylate or corresponding mixtures. The polyacrylic acid reads on carboxyvinyl polymer of claim 9. The hydrogel mixture further contains a polymer compound such as polyvinyl pyrrolidine having high affinity for polyhydric alcohol in the amount of 2.0% and a pharmaceutically acceptable diclofenac salt (page 4, line 1, 14).

The prior art of Donati et al

- a) differs from instant invention in the amount of water content in the composition and is silent with respect to a combination of magnesium hydroxide aluminum hydroxide co-precipitate and aluminum compound as crosslinking agents.
- b) is silent with respect to viscosity of (meth)acrylic acid-base polymer.

With respect to a), Ono et al teach an adhesive gel base containing water content in a range of 10 to 70%. Water contained in the adhesive gel base increases swelling of the skin and permeability of the drug (page 3, lines 26-28). In addition, Yamazaki et al teach a plaster capable of retaining tackiness for a long period, causing no swelling out or backside oozing during the storage and/or distribution after spreading the plaster, by blending specific crosslinking agents in a highly hydrous base containing an acrylic compound. The plaster is obtained by blending an acrylic compound with crosslinking agents aluminum magnesium hydroxide and aluminum hydroxide at a weight ratio A/B of 1:20 to 7:1 (abstract). Therefore, it would have been obvious to one skilled in the art at the time

invention was made to use water content in the range of claim 1 of instant invention and use a combination of aluminum magnesium hydroxide and aluminum hydroxide as crosslinkers and obtain a gel base with increased permeability of drug, retention of tackiness for a long period, no swelling out or backside oozing during storage and/or distribution.

With respect to b), given that the (meth)acrylate acid-base polymer is substantially similar to that of instant invention i.e. sodium polyacrylate meets the limitation of the ratio of formula (1) and (2), which is 100/0, and used for similar purposes, one of ordinary skill in the art would have a reasonable basis to believe that the (meth)acrylate acid-base polymer would exhibit similar property. Since PTO cannot conduct experiments, the burden of proof is shifted to the applicants to establish an unobviousness difference. See *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977).

9. Claims 12, 15, 17, 19 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Donati et al (EP 1 046 395) in view of Ono et al (EP 0 507 160 A1) and Yamazaki et al (JP 08-225443) as applied to claim 1 above, and further in view of Bernstein (EP 95512 A) or LaHann (US 4,313,958).

The discussion with respect to Donati et al in view of Ono et al and Yamazaki et al in paragraph 7 is incorporated herein by reference.

The prior art of Donati et al in view of Ono et al and Yamazaki et al is silent with respect to the addition of pharmaceutically active ingredient "capsaicin".

However, capsaicin is a well known pharmaceutically active ingredient as taught by Bernstein, where in the composition is used to treat psoriatic skin (abstract). Furthermore, LaHann teaches the usefulness of "capsaicin" as a potent analgesic (abstract). Therefore, it would have been obvious to one of ordinary skill in the art at the time invention was made to add "capsaicin" to the composition of Donati et al in view of Ono et al and thereby arrive at the claimed invention by realizing the above mentioned advantages.

10. Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Donati et al (EP 1046395).

Donati et al disclose a process for the preparation of hydrogel mixture consisting of thickening agent (sodium polyacrylate), wetting agent (polyhydric alcohols), cross-linking agent (Al compound) and water by mixing these and other optional ingredients in several stages. The process consists of adding polyhydric alcohol or wetting agent (sorbitol) to water. To this aqueous solution is added, in the form of aqueous solution, one half the quantity of cross-linking agent (dihydroxy aluminum glycinate), thickening agent (sodium polyacrylate). To this mixture thus obtained is added an aqueous mixture of optional ingredients such as polyvinyl pyrrolidone, (page 3, paragraph 0027; page 4, paragraph 0028-

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0030). Finally, an aqueous solution consisting of remaining parts of crosslinking agent, thickening agent and the active pharmaceutical agent are added. The water content of final composition is 29.73%, essentially the same as that described in the claims.

The prior art does not teach the same sequence of process steps as recited in the instant claim. The composition is taught by the prior art though the sequence of mixing components differs. However, it would have been obvious to one skilled in art at the time invention was made to alter the sequence and essentially arrive at the instant claim, absent evidence of unexpected results. See *In re Burhans*, 154 F.2d 690, 69 USPQ 330 (CCPA 1946) (selection of any order of performing process steps is prima facie obvious in the absence of new or unexpected results); *In re Gibson*, 39 F.2d 975, 5 USPQ 230 (CCPA 1930) (Selection of any order of mixing ingredients is prima facie obvious.).

11. Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Donati et al (EP 1 046 395 A1) in view of Ono et al (EP 0 507 160 A1).

Donati et al disclose a process for the preparation of hydrogel mixture consisting of thickening agent (sodium polyacrylate), wetting agent (polyhydric alcohols), cross-linking agent (Al compound) and water by mixing these and other optional ingredients in several stages. The process consists of adding polyhydric alcohol or wetting agent (sorbitol) to water. To this aqueous solution is added, in the form of aqueous solution, one half the quantity of cross-linking

agent (dihydroxy aluminum glycinate), thickening agent (sodium polyacrylate). To this mixture thus obtained is added an aqueous mixture of optional ingredients such as polyvinyl pyrrolidine, (page 3, paragraph 0027; page 4, paragraph 0028-0030). Finally, an aqueous solution consisting of remaining parts of crosslinking agent, thickening agent and the active pharmaceutical agent are added.

The prior art differs with respect to water content in the final composition and sequence of process steps.

However, the composition is substantially similar to that of the prior art though the sequence of mixing components differs. Therefore, it would have been obvious to one skilled in art at the time invention was made to alter the sequence and essentially arrive at the instant claim, absent evidence of unexpected results. See *In re Burhans*, 154 F.2d 690, 69 USPQ 330 (CCPA 1946) (selection of any order of performing process steps is prima facie obvious in the absence of new or unexpected results); *In re Gibson*, 39 F.2d 975, 5 USPQ 230 (CCPA 1930) (Selection of any order of mixing ingredients is prima facie obvious.).

As to the water content, prior art of Donati et al does not preclude using water content of the instant invention. Furthermore, Ono et al teach an adhesive gel base containing water content in a range of 10 to 70%. Water contained in the adhesive gel base increases swelling of the skin and permeability of the drug (page 3, lines 26-28). Therefore, it would have been obvious to one skilled in the art at the time invention was made to use water content in the range of claim 21

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of instant invention because Ono et al has proven successfully that permeability of drug increases at the said range of water content and one of ordinary skill in the art would expect the water content of Ono et al to work for the final composition of Donati et al in view of Ono et al, motivated by expectation of success and thereby realize increased permeability of the drug.

Response to Arguments

12. Applicant's arguments with respect to rejection of claims 2 and 14, under 35 U.S.C. 103(a) as being unpatentable over Donati et al (EP 1 046 395 A1) in view of Ono et al (EP 0 507 160 A1) and further in view of Sato et al (US 4,386,120), have been considered but are moot in view of the new ground(s) of rejection.
13. Applicant's arguments with respect to rejection of claims 21-22, under 35 U.S.C. 103(a) as being unpatentable over Donati et al (EP 1 046 395 A1) in view of Sato et al (US 4,386,120), have been considered but are moot in view of the new ground(s) of rejection.
14. Applicant's arguments with respect to rejection of claim 23, under 35 U.S.C. 103(a) as being unpatentable over Donati et al (EP 1 046 395 A1) in view of Sato et al (US 4,386,120) as applied to claim 21, and further in view of Bernstein (EP

95512 A) or LaHann (US 4,313,958), have been considered but are moot in view of the new ground(s) of rejection.

15. Applicant's arguments filed on August 9, 2007, in response to rejection of claim 13 under 35 U.S.C. 103(a) as being unpatentable over Donati et al (EP 1 046 395), have been fully considered but they are not persuasive.

In response to applicant's argument that process step (i.e. the step of adding polyhydric alcohol to (meth)acrylic acid-base polymer solution with a water content of 50% or more results in the polymer not getting aggregated) is recited in the claim, examiner's intention was to indicate that there is no reference to aggregation of polymers in the claim language. Even if it was included in the claim, selection of any order of mixing ingredients is still prima facie obvious because there is nothing on record to show that the step of adding polyhydric alcohol to (meth)acrylic acid-base polymer solution with a water content of 50% or more, results in the polymer not getting aggregated.

Applicant's further argue that as a result of the process, (meth)acrylic acid-base polymer can be readily dissolved and is therefore an indication that polymer does not get aggregated. It is the examiner's position that dissolution of polymer is a result of the ratio of acrylate and acrylic acid. Examiner points applicant to paragraph bridging pages 8-9 of specification, wherein it is pointed out that **acrylic content of 10 mol% or less results in the copolymer exhibiting good solubility in highly concentrated aqueous solution of polyhydric alcohol.**

Furthermore, applicant's indicated that invention is accomplished based on this finding.

16. Applicant's arguments filed on August 9, 2007, in response to rejection of claim 20 under 35 U.S.C. 103(a) as being unpatentable over Donati et al (EP 1046395) in view of Ono et al (EP 0 507 160 A1), have been fully considered but they are not persuasive.

The reasons provided in paragraph 14 are incorporated herein by reference.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karuna P. Reddy whose telephone number is (571) 272-6566.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Wu can be reached on (571) 272-1114. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public

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Karuna P Reddy
Examiner
Art Unit 1713

/KR/



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TECHNOLOGY PATENT EXAMINER
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